# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 6, 2019**

**Gemphire Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-37809** | **47-2389984** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**17199 N. Laurel Park Drive, Suite 401, Livonia, MI 48152**

(Address of principal executive offices) (Zip Code)

**(734) 245-1700**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

**Item 7.01 Regulation FD Disclosure.**

Beginning on January 7, 2019, Gemphire Therapeutics Inc. (the "Company") will host investor meetings. During the meetings, the Company will use the attached presentation to discuss the Company, its business plans and its product candidate, gemcabene. A copy of the presentation is furnished herewith as Exhibit 99.1 hereto.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Investor Presentation dated January 6, 2019. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

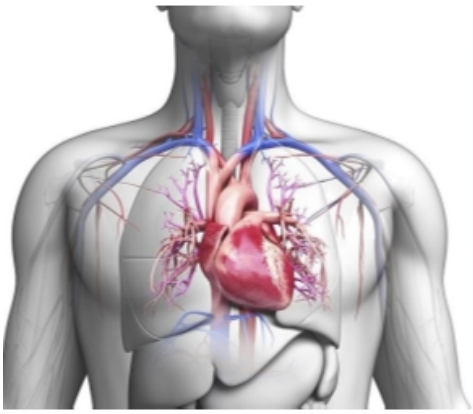
Dated: January 7, 2019

**GEMPHIRE THERAPEUTICS INC.**

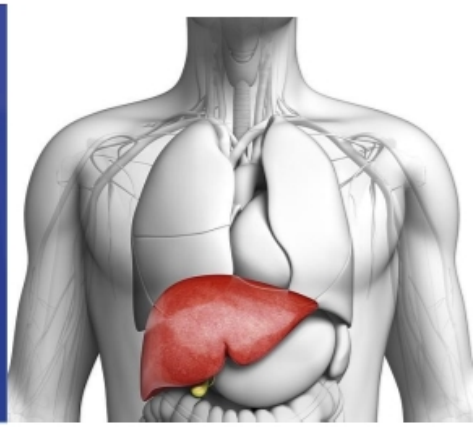
| | |
|---|---|
| By: | /s/ Dr. Steven Gullans |
| Name: | Dr. Steven Gullans |
| Title: | President and Chief Executive Officer |

Exhibit 99.1

Gemphire Therapeutics



ADVANCING
CARDIOVASCULAR
AND
NASH
OPPORTUNITIES



# CORPORATE PRESENTATION

January 2019

# Safe Harbor Statement

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects the Company's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "could", "would", "should", "plan", "predict", "potential", "project", "promising," "expect," "estimate," "anticipate," "intend," "goal," "strategy," "believe," "milestone," and similar expressions and variations thereof. Forward-looking statements may include statements regarding the Company's business strategy, market size, potential growth opportunities, capital requirements and use of proceeds, clinical development activities, the timing and results of clinical trials, regulatory submissions, potential regulatory approval and commercialization of the product candidate. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in our filings with the SEC. These forward-looking statements speak only as of the date of this presentation and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

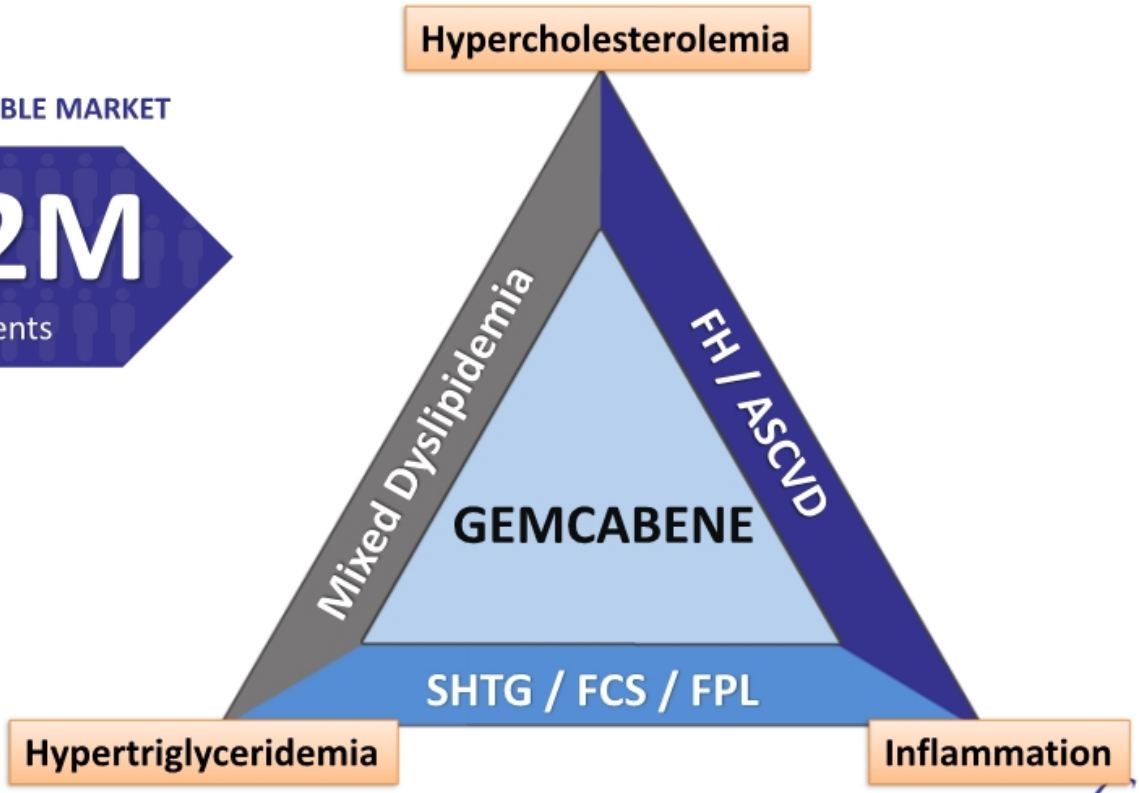
The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

# Gemcabene - Potential for Many Cardiometabolic Diseases

## Once Daily Tablet Observed to be a Safe "Add-On" to Statins and Other Lipid-Lowering Therapies in Trials to Date

ADDRESSABLE MARKET

~22M
Patients

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# Gemcabene Differentiated Product Profile

## Multiple Important Cardiometabolic Benefits to Patients Observed

### Significant Efficacy

- **LDL-C ~12-40% ↓**
- **TG ~20-50% ↓**
- **hsCRP ~25-50% ↓**

*Percentages (Mean and Median - LDL-C, Median - hsCRP, TG) have been demonstrated across multiple clinical studies in relevant patient populations*

### No Drug-Drug Interactions

- High dose atorvastatin
- High dose simvastatin
- Digoxin
- PCSK9 Inhibitors
- Ezetimibe

### Extensive Clinical Program

- > 1,110 subjects treated with gemcabene
- 23 completed Ph1 and Ph2 clinical trials
- Multiple cardiometabolic indications studied, including:
  - Severe Hypertriglyceridemia
  - ASCVD
  - Hypercholesterolemia
  - Familial Partial Lipodystrophy

### Promising Safety and Tolerability

- No myalgia as monotherapy
- No liver toxicities
- No significant affect on kidney function
- No QTc prolongation
- No clinically meaningful change in blood pressure
- No food effect



*A decrease in CRP (an earlier clinical assay) correlates with a decrease in hsCRP (the current CV risk assay).*

# Addressing the FDA Partial Clinical Hold

- Completing ***ongoing clinical trials of up to 6 months*** as allowed on partial clinical hold
- Hired additional ***regulatory & toxicology consultants*** to efficiently execute our plans
- *In vitro* PPAR-$\alpha$ ***transactivation study*** in dog and monkey is completed, per FDA request
- Initiated CRO-related activities to conduct 13 week ***PPAR-$\alpha$ knockout mouse study***, requested by FDA
- ***Submission*** of request to lift partial clinical hold to the ***FDA*** expected to occur in ***Q4'19***



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# Major Milestones for 2019

- ***Top-line clinical results*** from Phase 2 Familial Partial Lipodystrophy (FPL)/NASH trial (expected Q2)
- Submit preclinical toxicology report to FDA to ***address partial clinical hold*** (expected Q4)
- Conducting a review of a range of ***strategic alternatives*** with ***Ladenburg Thalmann*** as the strategic financial advisor, focused on maximizing stockholder value

# Gemcabene for Cardiometabolic Diseases

## Staged approach to multiple markets – "Orphan-First Strategy"

### Orphan Indications (>$500M Market)

- Familial Chylomicronemia Syndrome (FCS)
- Familial Partial Lipodystrophy (FPL)
- Homozygous Familial Hypercholesterolemia (HoFH)

### Broader Populations (>$5B Market)

- Severe Hypertriglyceridemia (SHTG) (TG ≥ 500 mg/dL)
- Heterozygous FH (HeFH) and ASCVD
- Mixed Dyslipidemia
- NAFLD/NASH

**Potential for Value Creation in Both Rare and Broad Cardiometabolic Patient Populations**



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# Rationale for "Orphan-First" Strategy

- **Large unmet clinical need:** FCS, FPL, and HoFH are considered orphan diseases and current therapies are inadequate
- **Smaller, less expensive trials:** Historically, these trials enroll fewer patients and FDA approvals have been based on surrogate endpoints (e.g., serum LDL-C or TGs)
- **Potential rapid path to market:** If approved, pursue rapid market entry with a targeted sales force addressing the most severe segment of dyslipidemia at an appropriate price point
- **Future potential to address much larger markets:** If approved, build on gemcabene's orphan branding to seek FDA approval for broader indications, such as SHTG and potentially ASCVD and NASH



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# Hypertriglyceridemia Opportunity

## Orphan Indications to Broad Indications

### Orphan

- Familial Partial Lipodystrophy (FPL) – 300 Pts, TGs >250 with other metabolic anomalies
- Familial Chylomicronemia Syndrome (FCS)- 1K Pts, TGs ≥750 mg/dL

### Broader Indications (Future)

- Severe Hypertriglyceridemia (SHTG) – 3M Pts, TGs ≥500 mg/dL
- ~60-70M Patients with highly elevated TGs ≥150 mg/dL

| Orphan Opportunity | Broader Market Opportunity |
|---|---|
| Gemcabene has potential to address large unmet need for patients facing morbidity and mortality concerns | Recent trials by others suggest lowering TGs and inflammation improves outcomes (MACE) |



*Sarwar N et al. Circulation. 2007;115:450-8; Christian et al. American Journal of Cardiology 2011: 107:891 CVRG; Trends in Elevated Triglyceride in Adults: United States, 2001–2012, NCHS Data Brief No. 198, May 2015; The National Organization for Rare Disease (https://rarediseases.org/); Cardiovascular Research Group (CVRG) 2018*

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# Recent News in Triglyceride Market

**Amarin: New Vascepa Prescriptions Grow After REDUCE-IT's Topline Results**

Nov. 9, 2018 12:29 PM ET

**Cardiovascular Death Reduced by 20%**
**Fatal or Nonfatal Heart Attacks Reduced by 31%**
**Fatal or Nonfatal Stroke Reduced by 28%**
**Urgent or Emergent Coronary Revascularization Reduced by 35%**
**Hospitalization for Unstable Angina Reduced by 32%**

**Vascepa® (icosapent ethyl) 26% Reduction in Key Secondary Composite Endpoint of Cardiovascular Death, Heart Attacks and Stroke Demonstrated in REDUCE-IT™ Supports 25% Overall Reduction in Five-Point Major Adverse Cardiovascular Event Primary Composite Endpoint**

November 10, 2018 15:00 ET

**FDA rejects Ionis Pharma and Akcea's volanesorsen for FCS**

Aug. 27, 2018 4:36 PM ET



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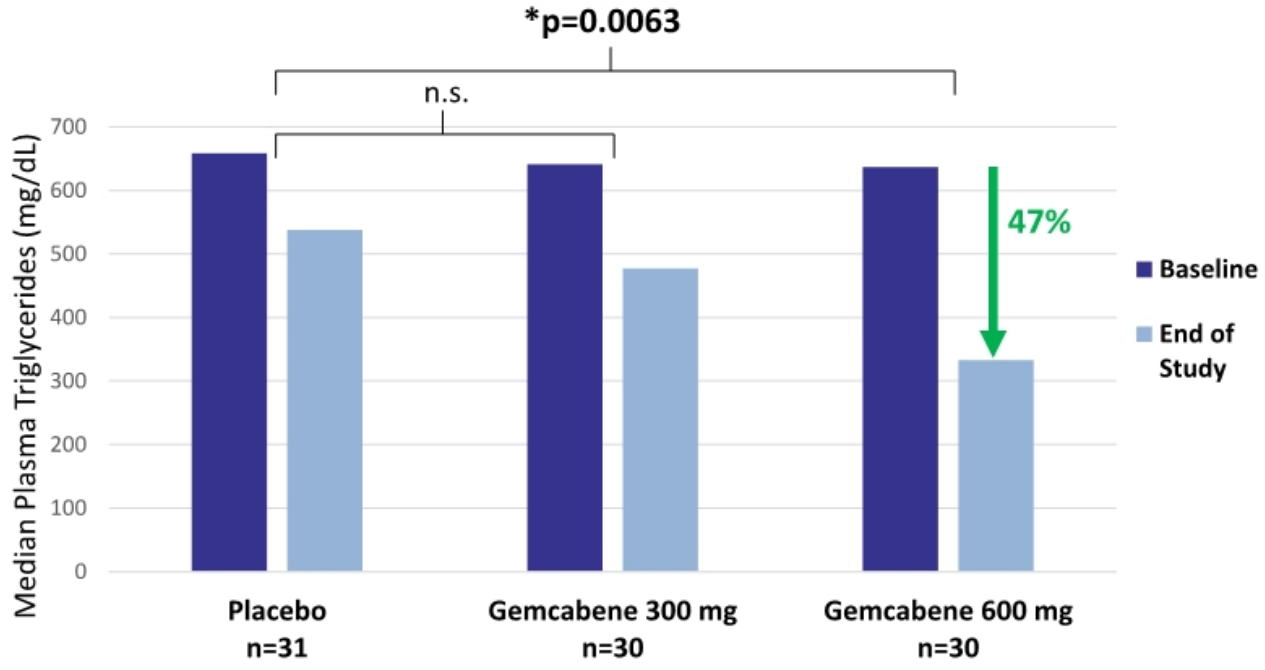
# Primary Endpoint: % Change in Serum TGs

## Significant Decrease in TGs Observed with Gemcabene 600 mg in INDIGO-1 Trial of Severe Hypertriglyceridemia (SHTG)




End of Study = Average of Week 10 and Week 12

*p-value based on Ranked ANCOVA

# Limitations of Current TG Therapies

## Disadvantages of Fish Oils, Fibrates, Niacin

**LARGE EXISTING MARKET DESPITE LIMITATIONS OF FIBRATES, FISH OILS & NIACIN**

| TG Lowering Agent | Treated Patients* 2017 Estimates |
|---|---|
| Fibrates | 3.8M patients/year |
| Fish Oils (Rx) | 810K patients/year |
| Fish Oils (OTC) | 18M patients/year |
| Niacin | 375K patients/year |

**Includes all indications; 2017 estimates from DRG Market Forecast Assumptions-Dyslipidemia (2016-2026)-September 2017 and NHIS Use of Complementary Health Approaches in the U.S., 2017*

## Competitor Limitations

- Food Effect & Compliance
  - **Prescription fish oil (i.e., EPA)**: 4g/day (4-8 capsules/day) taken multiple times during the day, GI discomfort
- Safety
  - **Fibrates**: Most used but product label contraindicates with statins; liver enzyme and LDL-C elevations
  - **Niacin**: Hepatotoxicity, tolerability flushing/itching/rash, may increase blood glucose level
- Lack of Efficacy
  - **OTC fish oil**
- Statin Add-on Needed
  - **Statins** are widely used but a **safe add-on** therapeutic is often needed



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# Familial Chylomicronemia Syndrome (FCS)

**Gemcabene has potential to benefit patients with life-threatening disease**

- A **rare disease** caused by genetic mutation(s) of the lipoprotein lipase (LPL) complex, leading to a **massive accumulation of chylomicrons in the blood**
- Diagnosis based on **fasting triglyceride levels ≥750 mg/dL**
- Patients often experience **recurrent abdominal pain and/or pancreatitis**
- FCS represents ~3000-5000 patients worldwide (~1000 in the US)
- There are currently **no FDA-approved treatments for FCS**
- There is a **high unmet need** for effective TG-lowering therapies for FCS patients

**Gemcabene's meaningful safety, tolerability, and broad ranging efficacy in prior studies has the potential to benefit a host of cardiometabolic patients, including those with FCS**



*The National Pancreas Foundation (https://pancreasfoundation.org/); Cardiovascular Research Group (CVRG) 2018*

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# Gemcabene Opportunity in FCS

## Efficient clinical trial path with no approved drugs on market

- Gemcabene has shown efficacy to lower TGs in multiple Phase 2 trials, including patients with TGs ≥750 mg/dL
- Prior FCS trials had an approvable endpoint of lowering TGs – no outcome trial was needed
- KOLs express need for a drug to safely and effectively treat FCS patients for TG reduction
- Potential for Orphan Designation
- No FDA approved products on market today

# Familial Partial Lipodystrophy (FPL)

**Significant potential for gemcabene to demonstrate effects on established measures of FPL**

- **FPL is a rare genetic disorder and orphan disease** characterized by an inability to store fat correctly, leading to a buildup of fat around all vital organs and in the blood
- FPL can lead to **loss of metabolic control** and these patients present with a variety of metabolic abnormalities, including **diabetes, hypertriglyceridemia, hypercholesterolemia, premature cardiovascular disease, hyperphagia, and NASH**
- The prevalence of FPL is estimated to be 1 in 1,000,000 in US
- Many patients are **statin intolerant** and use polypharmacy for their diabetes and lipid abnormalities with inadequate results



*The National Organization for Rare Disease (https://rarediseases.org/rare-diseases/familial-partial-lipodystrophy/)*

# Gemcabene Opportunity in FPL

- **Enrollment completed for Phase 2 open-label, 24 week trial** in FPL patients - investigator initiated study at the Univ. of Michigan
- **Top-line Phase 2 data**, including TG reduction and MRI-PDFF, expected in **Q2'19**
- To date, **no safety signals**
- Prior Phase 3 FPL trials recruited ~ 60 patients across well established centers of excellence
- Potential for **Orphan Designation**
- Current investigational therapies have observed toxicity issues



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# Exploring Regional Gemcabene Opportunities - China

- Recent regulatory changes in China favor US-China partnering, offering potentially faster regulatory times and preferences for innovative medications
- China ranks among the highest in prevalence of hypercholesterolemia and hypertriglyceridemia in the world
  - China has highest prevalence of hypertriglyceridemia (>200M pts)
  - HoFH in China is an significant unmet need and a larger population compared to the US
  - Heightened sensitivity to statins in the Asian population
- Gemphire is exploring regional partnering opportunities in China and will evaluate the feasibility for clinical collaborations



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# Gemcabene's Novel Mechanisms of Action

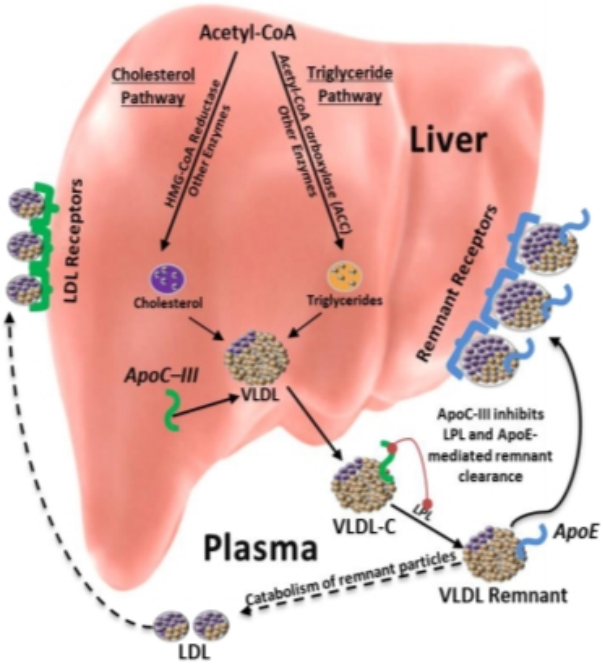
## Lowered LDL-C, TGs, ApoCIII, ApoB & hsCRP in Prior Trials
## Additive to Statin MOA

**IMPROVED CLEARANCE**

- Reduces ApoC-III gene expression and plasma ApoC-III protein levels
- Enhances VLDL-C clearance through increased affinity for the hepatic remnant receptor

**REDUCED PRODUCTION**

- Inhibits *de novo* synthesis of TGs and cholesterol in the liver
- TG effects due to inhibition of acetyl CoA carboxylase 1
- ↓VLDL-C particles leaves fewer apolipoproteins for catabolism to LDL-C




Not shown above, hsCRP is reduced via inhibition of gene transcription via blocking c/EBP binding



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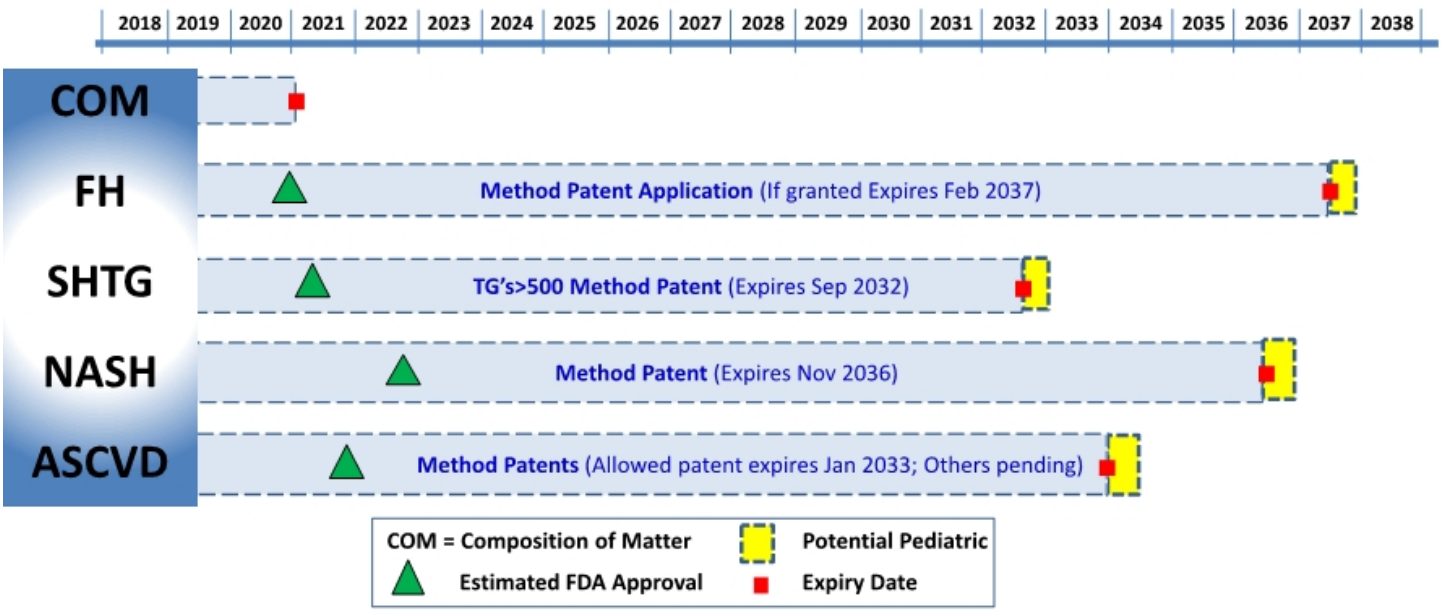
# Patent Protection for Gemcabene

## IP Protection for Indications and Long-Term Runway for Commercialization

### Protection by Year by Indication (US Market)




**POTENTIAL FOR REGULATORY EXCLUSIVITY FOR A NEW CHEMICAL ENTITY (NCE)**

US (5 years); US Orphan (FH) (7 years); Europe NCE or Orphan (10 years), Japan NCE (about 8 years); Japan Orphan (about 10 years); China (6 years); China Orphan (10 years)



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# Proven and Successful Management Team

| | |
|---|---|
| **Steve Gullans, PhD, FAHA**<br>Chief Executive Officer | EXCEL, RXGen, ClevelandHeartLab® Know your risk., Harvard Medical School |
| **Charles Bisgaier, PhD**<br>Chief Scientific Officer & Cofounder | Parke-Davis People Who Care, Esperion Therapeutics, Pfizer, ProNAi |
| **Seth Reno, MBA**<br>Chief Commercial Officer | AstraZeneca, MedImmune A member of the AstraZeneca Group, Wyeth Pharmaceuticals |
| **Rebecca Bakker-Arkema, RPh, MS, FAHA**<br>VP, Drug & Clinical Development | Parke-Davis People Who Care, Pfizer, alphacore pharma |

**Prior Marketed Products Experience**

CRESTOR® rosuvastatin calcium

Lopid® 600 (Gemfibrozil Tablets, USP)

LIPITOR atorvastatin calcium

myalept® (metreleptin) for injection

Lynparza™ olaparib

**Prior Pipeline Development Experience**

ETC-1002 and ETC-216 (Esperion)

ACP-501 (AstraZeneca/AlphaCore)

PNT-2258 (ProNAi)



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# Key Opinion Leaders Involved in Cardiometabolic Drug Development

## Clinical Advisors

| | |
|---|---|
| **John Kastelein, MD, PhD**<br>Amsterdam, Netherlands | University of Amsterdam |
| **Evan Stein, MD, PhD**<br>Illinois, USA | MEDPACE Reference Laboratories |
| **Rob Hegele, MD**<br>Toronto, Canada | University of Toronto |
| **Harold Bays, MD**<br>Kentucky, USA | |
| **Rohit Loomba, MD**<br>California, USA | UC San Diego Health |



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# Gemphire Capitalization and Coverage

| NASDAQ GLOBAL MARKET | |
|---|---|
| Symbol | GEMP |
| Market Cap[1] | ~$11.6M |
| Price Per Share[1] | $0.81/share |
| Shares Outstanding[2] | 14.3M |
| Cash at 9/30/18 | $23.8M |

| Institutional Ownership | Shares Held[3] |
|---|---|
| Venrock | 1,383K shares (10%) |
| BlackRock | 675K shares (5%) |
| Excel Venture Management | 930K shares (7%) |
| NorthPointe Capital, LLC | 482K shares (3%) |
| Pfizer | 675K shares (5%) |
| The Vanguard Group, Inc. | 382K shares (3%) |

## GEMP Analyst Coverage

**CANACCORD GENUITY INC.**
John Newman, Ph.D.

**JEFFERIES LLC**
Matthew J. Andrews*

**LAIDLAW & COMPANY**
Frank Brisebois

**PIPER JAFFRAY & CO**
Charles Duncan, Ph.D.*

**LIFESCI CAPITAL**
Patrick Dolezal

**RAYMOND JAMES & ASSOCIATES**
Laura Chico, Ph.D.

**ROTH CAPITAL PARTNERS**
Yasmeen Rahimi, Ph.D.

*1. At 1/3/19 2. At 9/30/18, Fully Diluted Shares Outstanding = 18.1M; 3. Shares Held at 9/30/18 or most recent reported shares (Percentage Ownership Calculated on Shares Outstanding at 9/30/18)*

** New coverage assignment pending*



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# APPENDIX

# Gemcabene Opportunity in SHTG

## Product Profile and Path to Market

- Once-daily, oral pill
- No observed food effect, unlike fish oils
- Safety and tolerability in >1100 trial subjects
- Observed to safely combine with statins and other drugs
- Serum TG has been an FDA approvable endpoint for patients with TGs ≥500 mg/dL; with no outcome trial required; same path used for Vascepa™, gemfibrozil and fenofibrate
- Issued US and Worldwide method patents valid into 2032

**Gemcabene's promising safety, tolerability, and broad ranging efficacy in prior studies has the potential to benefit a host of cardiometabolic patients, including those with SHTG**



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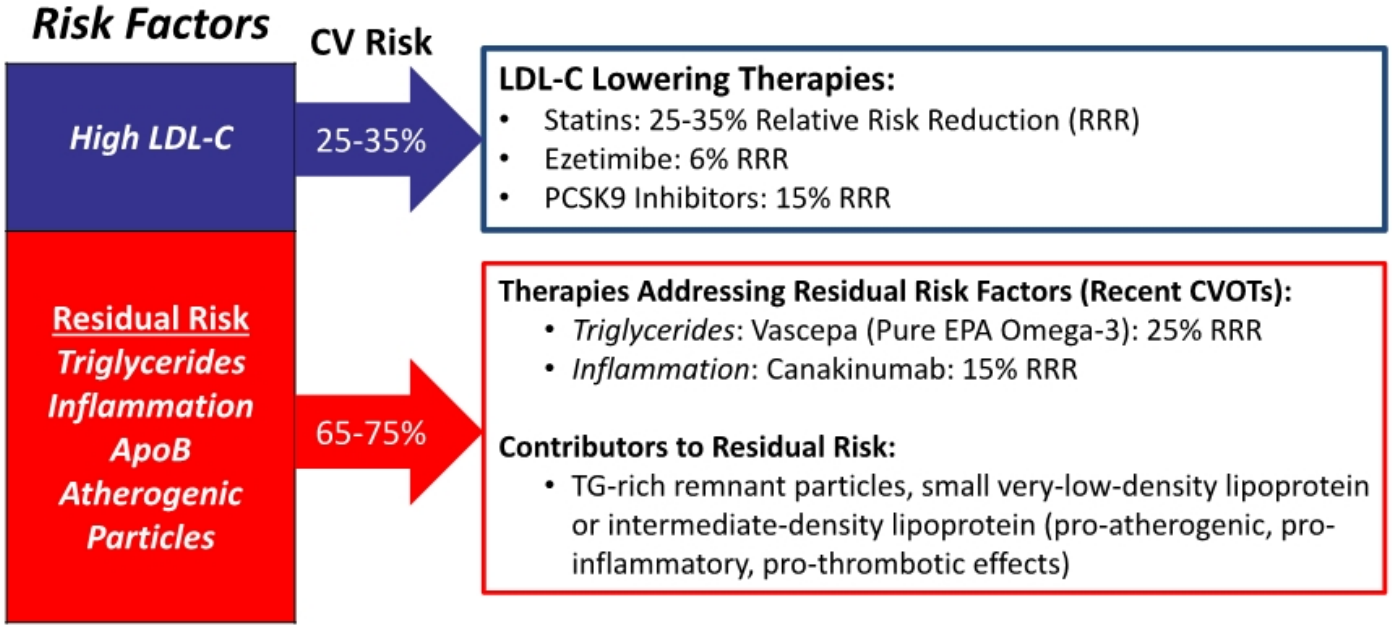
# REDUCTION OF RESIDUAL RISK FACTORS

## Including: Cholesterol-Rich VLDL-Remnants and Inflammation

### Despite marked advances in LDL lowering, people still die from CV disease




**Gemcabene May Address Residual CV Risk by Lowering LDL-C, TG, and hsCRP**



*Ganda, O.P. et al. J Am Coll Cardiol. 2018;72(3):330–43; company presentations*

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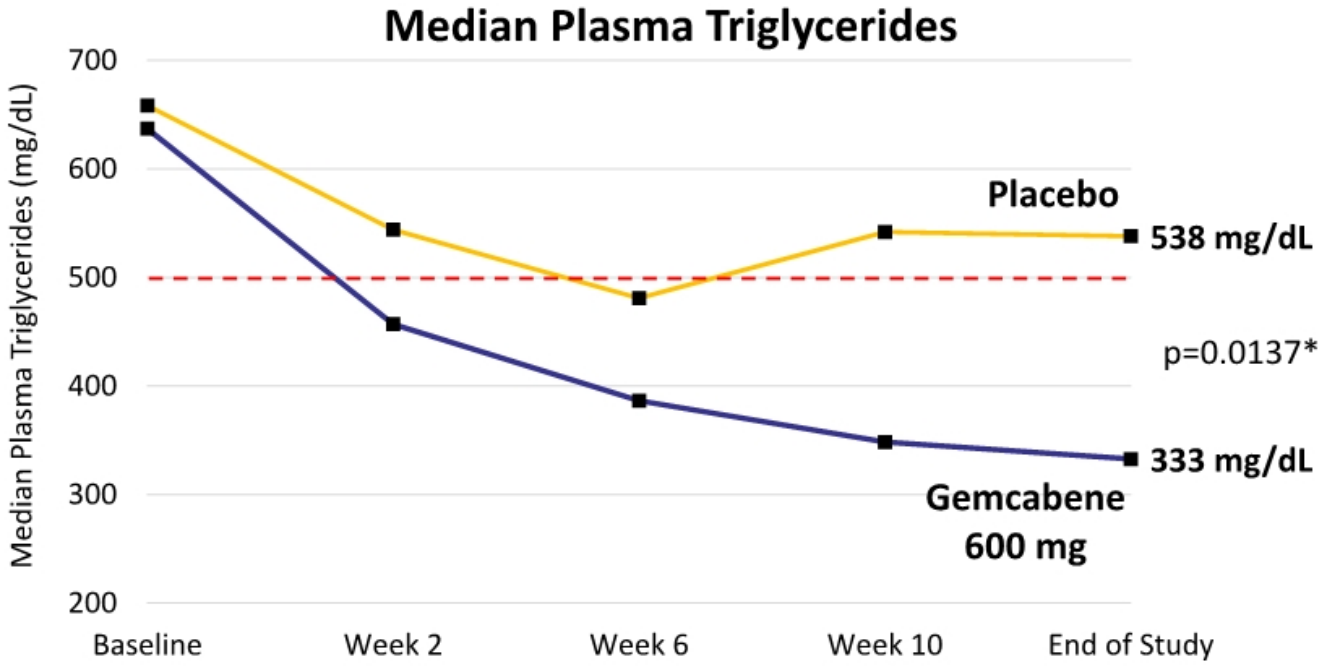
# Absolute Levels of TGs In INDIGO-1

## Lower TG level in the 600 mg Group vs Placebo at End of Study






*Ranked ANCOVA p-value for the placebo-adjusted difference of 600 mg vs placebo

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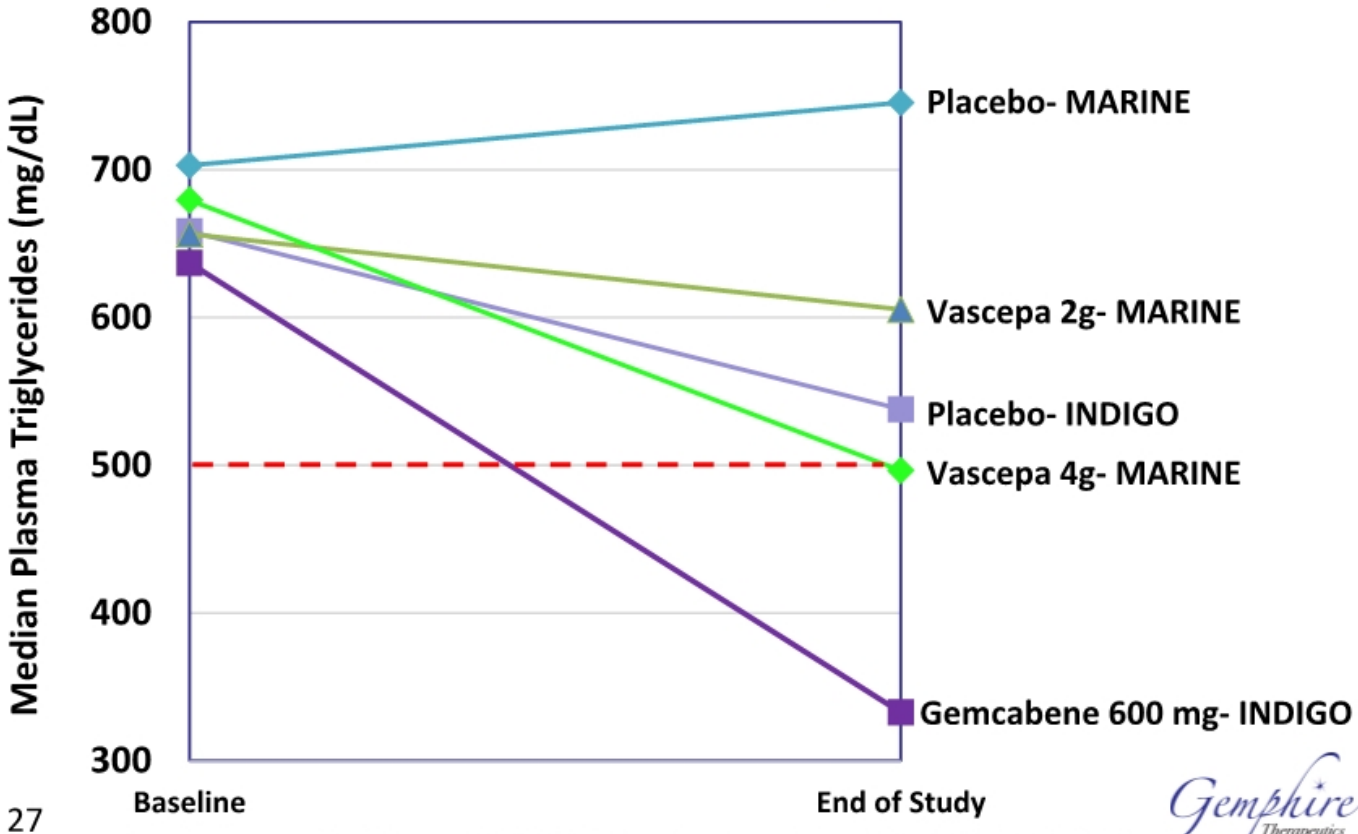
# Gemcabene (Indigo) Compared to Vascepa (Marine)

## Treatment Goal for SHTG is TGs <500 mg/dL






*American Journal of Cardiology 2003;92:538–543; American Journal of Cardiology 2011; 108:682–690*

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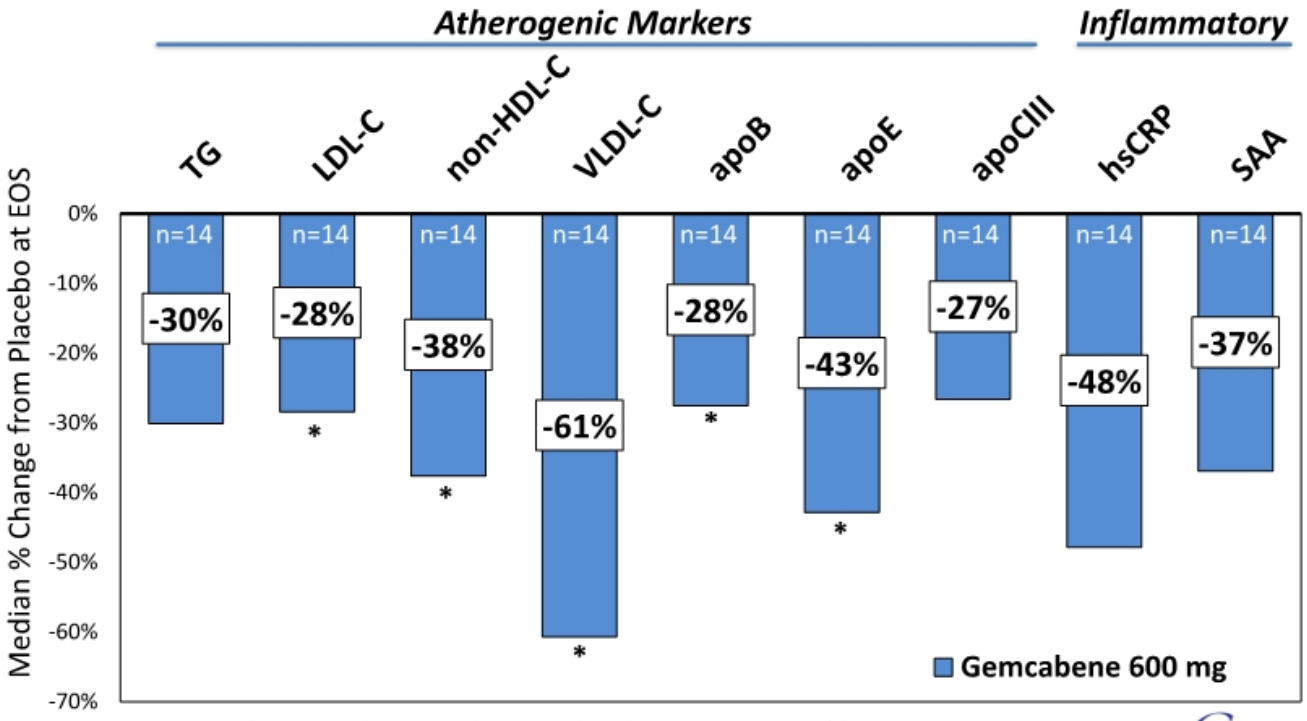
# Gemcabene Reduces Atherogenic and Inflammatory Markers that May Reduce Residual Risk in Patients^

## Lipid and Inflammatory Marker Reductions Observed in INDIGO-1

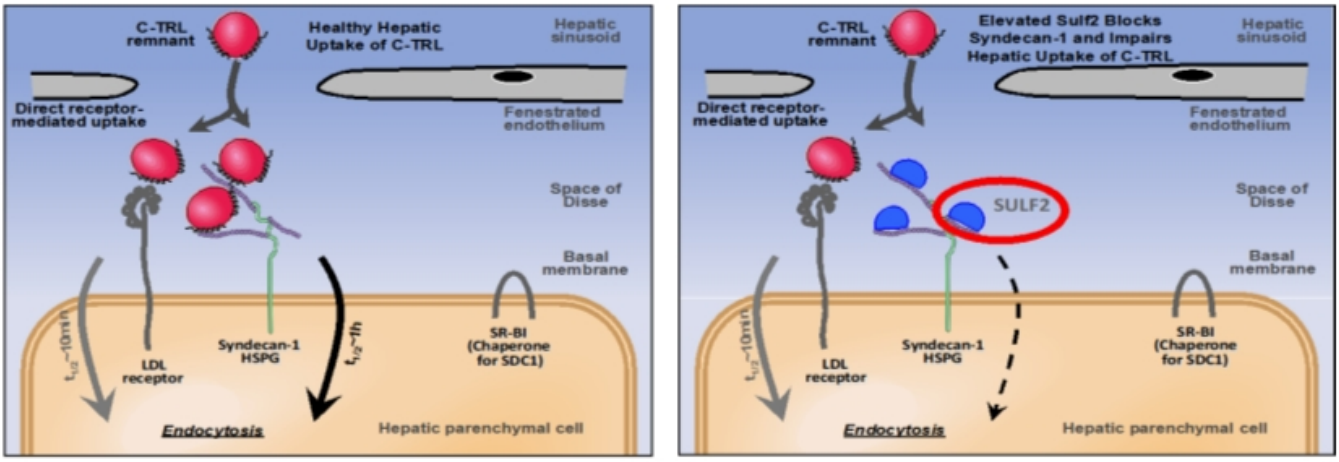



^Subset of patients from INDIGO-1 trial with LDL-C ≥100 mg/dL and TGs ≥ 200 mg/dL

* Ranked ANCOVA p<0.05

# Gemcabene Appears to Upregulate VLDL-receptor (Syndecan-1 receptor) via Inhibition of Sulfatase II

***Gemcabene, which has been shown to lower plasma ApoB-lipoprotein concentrations in mice and human trials, appears to regulate remnant receptor via SULF2 in the liver***



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